



OHRS Information Sheet

Discussing Enrollment in a Clinical or Non-Clinical Trial with Prospective Participants: Keys to Successful Communication

This OHRS Information Sheet provides guidance to investigators on having a successful conversation with prospective participants about enrollment in a Dana-Farber/Harvard Cancer Center (DF/HCC) clinical or non-clinical trial. The following information outlines some questions to consider and steps to follow when talking to a patient about the possibility of enrolling in a clinical or non-clinical trial. This information is taken from current National Cancer Institute (NCI) guidance (http://www.nih.gov/health/clinicaltrials/providers/tips.htm).

The Sequenced Approach to Successful Communication

When speaking with a potential participant about the possibility of enrolling in a clinical or non-clinical trial at one of the DF/HCC institutions, it is important to follow a sequence of steps in order to promote open-communication and ensure complete understanding for the prospective participant:

Setting the Stage

Empowerment, Respect, and Understanding

Foster empowerment by inviting the participant to choose who will attend this discussion. Hold the meeting in a private location where there will be no interruptions.

Communicate respect, empathy, and importance of discussion by acknowledging trauma of diagnosis. Provide pen and paper to the prospective participant and invite comments, questions, thoughts, and feelings.



Step 1

Ensure Patient Understanding of Disease

Simplify information and avoid medical jargon or "laundry lists" of side effects and medications.

Summarize often and repeat important points as many times as necessary.

Stress the importance of information-seeking and ask open-ended questions.

Avoid interrupting and check that all questions were answered to the prospective participant's satisfaction.



Step 2

Describe the Current Best Proven Treatment

Follow all points in Step 1 when describing the current best proven treatment to prospective participants. Explain that disease treatments have improved over time due to clinical research and participation. Avoid pushing the recommendation of a clinical trial, but be prepared to respond accordingly if asked.



Step 3

Present the Option of the Clinical or Non-Clinical Trial

Break the informed consent discussion into two meetings if this may enhance participant understanding. Discuss current treatment options and explain how the clinical trial differs from standard treatment.

Explain at least three times that participation is completely voluntary.

Explain the right to withdraw at any time.

Discuss any potential conflicts of interest that you may have as an investigator.

Be prepared to answer if the prospective participant asks if you would personally enroll in the trial or if you would advise a family member to enroll in the trial.